UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF MISSISSIPPI

HUBERT RICHARDSON as Personal Representative for KEMETHA RICHARDSON, deceased PLAINTIFF, V. KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; PHILIPS HOLDING USA, INC.; and PHILIPS RS NORTH AMERICA LLC; DEFENDANTS.	)	Civil Action No. 1:21-CV-185-DMB-DAS **JURY DEMAND**

COMPLAINT

Plaintiff Hubert Richardson, as personal representative for Kemetha Richardson, by and through his undersigned counsel, hereby submits the following Complaint and Demand for Jury Trial against Defendants Koninklijke Philips N.V. ("Royal Philips"), Philips North America LLC ("Philips NA"), Philips Holding USA, Inc. ("PHUSA"), and Philips RS North America LLC ("Philips RS") (collectively referred to as "Philips" or the "Defendants") and alleges the following upon personal knowledge and belief, and investigation of counsel:

INTRODUCTION

1. Philips manufactures, markets, sells, and distributes a variety of products for sleep and home respiratory care.

2. Philips manufactures, markets, imports, sells, and distributes a variety of Continuous Positive Airway Pressure (CPAP) and BiLevel Positive Airway Pressure (BiLevel PAP) devices for patients with obstructive sleep apnea ("OSA").

3. Philips also manufactures, markets, imports, sells, and distributes a variety of ventilator devices for patients with respiratory conditions.

4. On June 14, 2021, Philips issued a recall notification for many of its CPAP and BiLevel PAP devices as well as a number of its ventilator devices.

5. In its recall notification, Philips advised of potential health risks related to the sound abatement foam used in the affected devices.

6. Philips informed patients using these affected devices of potential risks from exposure to degraded sound abatement foam particles and exposure to chemical emissions from the sound abatement foam material.

7. Specifically, Philips notified patients that the risks related to issues with the sound abatement foam include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects.

8. Kemetha Richardson was prescribed and purchased the DreamStation CPAP device, one of Philips' recalled devices, to treat her obstructive sleep apnea.

9. Kemetha Richardson used Philips' DreamStation CPAP device (the "subject device"), one of Philips' recalled devices, on a daily basis for a number of years.

10. In or around November 2018, Kemetha Richardson was diagnosed with liver disease.

11. As a direct and proximate result of Philips' conduct, Kemetha Richardson has suffered serious and substantial life-altering injuries including death on December 14, 2108.

12. As a direct and proximate result of the subject device, manufactured, marketed, imported, sold, and distributed by Philips, Kemetha Richardson suffered physical, and financial injuries, including liver disease and death.

PLAINTIFF

13. Plaintiff Hubert Richardson as personal representative of the estate of Kemetha Richardson is over nineteen (19) years of age and is a resident citizen of the State of Alabama. Plaintiff has been appointed by the probate court of Lowndes County, Mississippi, as personal representative of the estate of Kemetha Richardson. The claims on behalf of Kemetha Richardson's estate are brough pursuant to Mississippi's wrongful death statute, Miss. Code Ann. §11-7-13.

14. Kemetha Richardson was a resident and citizen of Columbus, Mississippi since the time she was prescribed her Philip's DreamStation CPAP through the time she was diagnosed with liver disease and the date of her death.

DEFENDANTS

15. Defendant Koninklijke Philips N.V. ("Royal Philips") is a public limited liability company established under the laws of The Netherlands, having its principal executive offices at Philips Center, Amstelplein 2, 1096 BC Amsterdam, The Netherlands. Royal Philips is the parent company of Philips NA and Philips RS. Royal Philips can be served with process via the *Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters* ("Hague Service Convention").

16. Defendant Philips North America LLC ("Philips NA") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly-owned subsidiary of Royal Philips. Upon information and belief, Philips NA manages the operation of Royal Philips' various lines of business, including Philips RS, in North America. The sole member of Philips NA is PHUSA, which is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts

02141. Philips NA may be served through its registered agent, Corporation Service Company, at 7716 Old Canton Road, Suite C, Madison, MS 39110.

17. Defendant Philips Holding USA, Inc. ("PHUSA") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. PHUSA is a holding company that is the sole member of Defendant Philips NA. PHUSA may be served through its registered agent, Corporation Service Company, at 7716 Old Canton Road, Suite C, Madison, MS 39110.

18. Defendant Philips RS North America LLC ("Philips RS") is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.[1] Philips RS may be served through its registered agent, Corporation Service Company, at 7716 Old Canton Road, Suite C, Madison, MS 39110.

19. Royal Philips, Philips NA, PHUSA, and Philips RS are hereinafter collectively referred to as "Philips" or the "Defendants."

JURISDICTION AND VENUE

20. At all times pertinent to this Complaint, Defendants were and are in the business of designing, manufacturing, marketing, promoting, advertising, and selling devices for the treatment of obstructive sleep apnea, including the DreamStation device prescribed for and purchased by Kemetha Richardson at issue in this lawsuit (the "subject device").

21. At all times pertinent to this Complaint, Defendants were the mere alter egos or instrumentalities of each other. There is such a unity of interest and ownership between

[1] *Philips announces completion of tender offer to acquire Respironics*, WEB WIRE, https://www.webwire.com/ViewPressRel.asp?aId=61199 (accessed June 30, 2021).

Defendants that the separate personalities of their entities ceased to exist. Defendants operated as a single enterprise, equally controlled each other's business affairs, commingled their assets and funds, disregarded corporate formalities, and used each other as a corporate shield to defeat justice, perpetuate fraud and evade contractual and/or tort liability.

22. At all times pertinent to this Complaint, Defendants acted in all respects as agents or apparent agents of one another.

23. At all times pertinent to this Complaint, Defendants acted in concert in the designing, manufacturing, marketing, promoting, advertising, and selling of devices for the treatment of obstructive sleep apnea, including the subject device. Defendants combined their property and labor in a joint undertaking for profit, with rights of mutual control over each other, rendering them jointly liable to Plaintiff.

24. Defendants regularly transact business in Mississippi that includes marketing and selling devices for the treatment of obstructive sleep apnea, derive substantial revenue from their business transactions in Mississippi, and have purposely availed themselves of the privilege of doing business in Mississippi.

25. Defendants shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to Mississippi through the stream of commerce.

26. Defendants' actions in marketing and selling their devices in Mississippi should have led them to reasonably anticipate being hauled into Court in Mississippi.

27. Defendants have sufficient "minimum contacts" with Mississippi that subjecting them to personal jurisdiction in Mississippi does not offend traditional notions of fair play and substantial justice.

28. As detailed below, Kemetha Richardson suffered injuries in Lowndes County, Mississippi from the subject device that Defendants negligently designed and/or manufactured either in Mississippi or outside of Mississippi. Thus, Defendants committed a tort either in Mississippi or outside of Mississippi that caused injuries in Mississippi, and the Court has personal jurisdiction over Defendants under Mississippi's Long Arm Statute, Miss. Code Ann. § 13-3-57.

29. This Court has personal jurisdiction over Philips NA, PHUSA, and Philips RS because of their systematic and continuous contacts with Mississippi as well as their maintenance of a registered agent for service of process in Mississippi.

30. This Court has personal jurisdiction over Royal Philips because of its systematic and continuous contacts with Mississippi.

31. This Court has original jurisdiction in this matter pursuant to 28 U.S.C. §1332(a)(1) and §1332(a)(2), as there is complete diversity between Plaintiff and Defendants and the amount in controversy exceeds $75,000.

32. There is complete diversity between Plaintiff and all of the members comprising Philips NA and Philips RS.

33. This Court is a proper venue for this civil action pursuant to 28 U.S.C § 1391(b)(2) as the event giving rise to the Plaintiff's claims occurred in Lowndes County, Mississippi.

34. This Court's exercise of personal jurisdiction over Defendants comports with due process.

BACKGROUND

35. At all relevant times, Defendants manufactured, marketed, sold, and distributed a lineup of CPAP and BiPAP devices as well as ventilator devices under its "Sleep & Respiratory

Care" portfolio. These devices are designed to assist individuals with a number of sleep, breathing, and other respiratory conditions, including sleep apnea.

36. Defendants sought and obtained Food and Drug Administration ("FDA") approval to market the Recalled Devices, including the subject device used by Kemetha Richardson, under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

A. Continuous Positive Airway Pressure Therapy

37. Continuous Positive Airway Pressure ("CPAP") therapy is a common nonsurgical treatment primarily used to treat sleep apnea. CPAP therapy typically involves the use of a nasal or facemask device and a CPAP device helps individuals breathe by increasing the air pressure in an individual's throat.

38. Sleep Apnea is a common sleep disorder characterized by repeated interruptions in breathing throughout an individual's sleep cycle. These interruptions, called "apneas," are caused when the soft tissue in an individual's airway collapses. The airway collapse prevents oxygen from reaching the individual's lungs which can cause a buildup of carbon dioxide. If the individual's brain senses the buildup of carbon dioxide, it will briefly rouse the individual from sleep so that the individual's airway can reopen. Often these interruptions are so brief that the individual will not remember. Despite the brevity of the interruptions, the sleep cycle disruption caused by sleep apnea can dramatically impact a person's lifestyle, including negatively impacting energy, mental performance, and long-term health. CPAP therapy helps treat sleep apnea by

preventing the person's airway from collapsing while breathing during sleep cycles, which can help prevent interruptions in breathing.

B. Bi-Level Positive Airway Pressure Therapy

39. Bi-Level Positive Airway Pressure ("BiPAP") therapy is a common alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy, BiPAP therapy is nonsurgical and involves the use of a nasal or facemask device to maintain air pressure in an individual's airway. BiPAP is distinguishable from CPAP therapy, however, because BiPAP devices deliver two alternating levels—inspiratory and expiratory—of pressurized air into a person's airway, rather than the single continuous level of pressurized air delivered by a CPAP device. The inspiratory positive airway pressure assists a person as a breath is taken in. Conversely, the expiratory positive airway pressure is applied to allow a person to comfortably breathe out. BiPAP devices deliver one level of pressurize air (the inspiratory positive level) to assist as a person inhales, and another level (the expiratory level) as a person exhales.

C. Philips' Sleep & Respiratory Care Devices Were Endangering its Users

40. On April 26, 2021, as part of its Quarterly Report for Q1 2021, Philips disclosed for the first time, under a section entitled "Regulatory Update," that device user reports had led to a discovery that the type of PE-PUR "sound abatement" foam Philips used to minimize noise in several CPAP and BiPAP respirators posed health risks to its users. Specifically, Philips disclosed that "the [PE-PUR] foam may degrade under certain circumstances, influenced by factors

including use of unapproved cleaning methods, such as ozone[], and certain environmental conditions involving high humidity and temperature."[2]

41. Philips has utilized polyester-based polyurethane (PE-PUR) sound abatement foam to dampen device vibration and sound during routine operation.

42. On June 14, 2021, as a result of extensive ongoing review following the announcement on April 26, 2021, Philips issued a recall notification for specific affected devices.[3]

43. In its recall notification, Philips identified examples of potential risks which include exposure to degraded sound abatement foam particles and exposure to chemical emissions from the sound abatement foam material.[4]

44. Philips reported that, based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment.[5]

45. According to Philips' recall notice, the PE-PUR Foam used in Recalled Devices puts Recalled Device users at risk of suffering from the following health harms: "*Particulate exposure* can cause headache, irritation [skin, eye, and respiratory tract], inflammation, respiratory

---

[2] *First Quarter Results*, PHILIPS (Apr. 26 2021), https://www.results.philips.com/publications/q121/downloads/pdf/en/philips-first-quarter-results-2021-report.pdf (accessed June 30, 2021).
[3] *Medical Device recall notification (U.S. only) / field safety notice (International Markets)*, PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2 (accessed June 30, 2021).
[4] *Philips issues recall notification*, PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html (accessed June 30, 2021) (emphasis added).
[5] *Id.*

issues, and possible toxic and carcinogenic effects[;]" whereas the "potential risks of *chemical exposure due to off-gassing* include headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and *carcinogenic* effects."[6]

46. On June 14, 2021, Philips also issued a brief report titled "Clinical Information for Physicians." In this report, Philips disclosed that "[l]ab analysis of the degraded foam reveals the presence of potentially harmful chemicals including Toluene Diamine, Toluene Diisocyanate, and Diethylene glycol."[7]

47. In its report titled "Clinical Information for Physicians," Philips also disclosed that lab testing performed by and for Philips has also identified the presence of Volatile Organic Compounds (VOCS) which may be emitted from the sound abatement foam component of the affected devices. "VOCs are emitted as gases from the foam included in the [affected devices] and may have short- and long-term adverse health effects. Standard testing identified two compounds of concern may be emitted from the foam that are outside of safety thresholds. The compounds identified are the following: Dimethyl Diazine and Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)-"[8].

---

[6] *Philips issues recall notification*, PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html (accessed June 30, 2021) (emphasis added).

[7] *Sleep and Respiratory Care update, Clinical information for physicians*, PHILIPS (June 14, 2021), https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-clinical-information-for-physicians-and-providers.pdf?_ga=2.43039205.1759564883.1625006706212130326.1624473291&_gl=1*2nhu1w*_ga*MjEyMTMwMzI2LjE2MjQ0NzMyOTE.*_ga_2NMXNNS6LE*MTYyNTE1MTQ3MC4xNi4xLjE2MjUxNTE1OTUuMTg. (accessed June 30, 2021).

[8] *Id.*

D. Philips' Recalled Devices

48. In total, Philips announced that "[b]etween 3 million and 4 million" devices are targeted in the recall.[9]

49. The list of the devices recalled by Phillips (the "Recalled Devices") include:

Philips CPAP and BiLevel PAP Devices Subject to Recall[10]	
Device Name/Model	**Type**
Philips E30 (Emergency Use Authorization)	Continuous Ventilator, Minimum Ventilatory Support, Facility Use
Philips DreamStation ASV	Continuous Ventilator, Non-life Supporting
Philips DreamStation ST, AVAPS	Continuous Ventilator, Non-life Supporting
Philips SystemOne ASV4	Continuous Ventilator, Non-life Supporting
Philips C Series ASV, S/T, AVAPS	Continuous Ventilator, Non-life Supporting
Philips OmniLab Advanced Plus, In-Lab Titration Device	Continuous Ventilator, Non-life Supporting
Philips SystemOne (Q Series)	Non-continuous Ventilator
Philips DreamStation, CPAP, Auto CPAP, BiPAP)	Non-continuous Ventilator
Philips DreamStation GO, CPAP, APAP	Non-continuous Ventilator
Philips Dorma 400, 500, CPAP	Non-continuous Ventilator
Philips REMStar SE Auto, CPAP	Non-continuous Ventilator

[9] Associated Press, *Philips recalls ventilators, sleep apnea machines due to health risks*, NBC NEWS, https://www.nbcnews.com/business/consumer/philips-recalls-ventilators-sleep-apnea-machines-due-health-risks-n1270725 (accessed June 29, 2021).

[10] *Medical Device recall notification (U.S. only) / field safety notice (International Markets)*, PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2 (accessed June 30, 2021).

Philips Mechanical Respirator Devices Subject to Recall[11]	
Philips Device Name/Model	**Type**
Philips Trilogy 100 Ventilator	Continuous Ventilator
Philips Trilogy 200 Ventilator	Continuous Ventilator
Philips Garbin Plus, Aeris, LifeVent Ventilator	Continuous Ventilator
Philips A-Series BiPAP Hybrid A30	Continuous Ventilator, Minimum Ventilatory Support, Facility Use
Philips A-Series BiPAP V30 Auto Ventilator	Continuous Ventilator, Minimum Ventilatory Support, Facility Use
Philips A-Series BiPAP A40	Continuous Ventilator, Non-life Supporting
Philips A-Series BiPAP A30	Continuous Ventilator, Non-life Supporting

50. Philips issued the following advice to patients using any of the Recalled Devices:

- "For patients using BiLevel PAP and CPAP devices: Discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks."[12]
- "For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps."[13]

E. Philips Unreasonably Delayed its Recall

51. Defendants have not disclosed when they first received reports from users of its Sleep & Respiratory Care devices "regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)."[14] However,

[11] *Id.*
[12] *Id.* (emphasis in original).
[13] *Id.* (emphasis in original).
[14] *Medical Device recall notification (U.S. only) / field safety notice (International Markets)*, PHILIPS RESPIRONICS https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2 (accessed June 30, 2021).

given how long ago the first of the Recalled Devices came to market, it is unlikely that Defendants only recently learned of these issues.

52. Thus, as a result of user reports and other testing performed by and on behalf of Defendants, Defendants were aware of the degradation of the PE-PUR sound abatement foam used in the Recalled Devices, yet continued to manufacture, market, and sell the Recalled Devices with such awareness for a significant period of time. During this period, Defendants unreasonably and unjustly profited from the manufacture and sale of the Recalled Devices and unreasonably put users of the Recalled Devices at risk of developing adverse health effects, including liver disease.

KEMETHA RICHARDSON

53. Kemetha Richardson was an adult resident and citizen of Columbus, Mississippi. Kemetha Richardson was been a resident a citizen of Columbus, Mississippi at all relevant times to this action.

54. At or around May 2016, Kemetha Richardson was prescribed the use of and purchased a DreamStation device (the "subject device"). The subject device prescribed for and purchased by Kemetha Richardson was one of the Recalled Devices.

55. At the time Kemetha Richardson was prescribed the use of and purchased the subject device, she was a resident and citizen of Lowndes County, Mississippi.

56. Kemetha Richardson used the subject device daily to treat her sleep apnea. At all times Kemetha Richarson used the subject device, she used the subject device in accordance with the guidelines, manual, and instructions for use set forth by Defendants.

57. Kemetha Richardson used the subject device at all times for a purpose for which the subject device was marketed, designed, and intended.

58. At all times Kemetha Richardson used the subject device in accordance with the directions and instructions issued by her physician who prescribed the use of the subject device.

59. As a result of using the subject device, Kemetha Richardson suffered personal injuries including liver disease and death. These injuries would not have occurred but for the defective nature of the subject device and/or Defendants' wrongful conduct.

60. Kemetha Richardson was diagnosed with liver disease on or around November 2018.

61. Kemetha Richardson's use of the subject device caused or significantly contributed to her development and progression of liver disease which led to her death in December 2018.

62. By reason of the foregoing, Kemetha Richardson wrongfully died due to the defective nature of the subject device and/or Defendants' wrongful conduct.

63. As a result of the aforesaid conduct and subject device manufactured, designed, sold, distributed, advertised, and promoted by Defendants, Kemetha Richardson was injured, resulting in severe mental and physical pain and suffering. Such injuries were cause for death.

CAUSES OF ACTION

COUNT I
STRICT PRODUCTS LIABILITY – DESIGN DEFECT

64. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

65. Plaintiff pleads this count under Mississippi's product liability act, Miss. Code. Ann. §11-1-63.

66. At all times herein mentioned, Defendants were involved in researching, designing, developing, manufacturing, testing, selling and/or distributing the Recalled Devices, including the subject device, which are defective and unreasonably dangerous.

67. The subject device is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design. The subject device is defective in design because it causes headaches, irritation of the skin, eye, and respiratory tract, inflammation respiratory issues, asthma, adverse effect to organs (including the kidneys and liver), hypersensitivity, nausea, vomiting, and toxic and carcinogenic effects. It is more dangerous than other available devices indicated for similar conditions and uses, and the utility of the device does not outweigh its risks.

68. The defective condition of the subject device rendered it unreasonably dangerous and/or not reasonably safe, and the device was in this defective condition at the time it left the hands of Defendants. Subject device was expected to and reached Kemetha Richardson and her physician without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied, and otherwise released into the stream of commerce.

69. The subject device was used for its intended purposes by Kemetha Richardson and the subject device was not materially altered or modified prior to its use.

70. The subject device is defective in design because the PE-PUR foam comprising part of the device can degrade into particles that enter the device's air pathway and can off-gas certain chemicals. These characteristics cause, among other problems, liver disease.

71. At or before the time the subject device was released on the market and/or sold to Kemetha Richardson, Defendants could have designed the product to make it less prone to causing

the above listed health harms, a technically feasible safer alternative design that would have prevented the harm Kemetha Richardson suffered without substantially impairing the function of the device.

72. Kemetha Richardson was not able to discover, nor could she have discovered through the exercise of reasonable diligence, the defective nature of the subject device. Further, in no way could Kemetha Richardson have known that Defendants had designed, developed, and manufactured the subject device in a way as to make the risk of harm or injury outweigh any benefits.

73. The subject device is and was being used in a way which the Defendants intended at the time it was prescribed to Kemetha Richardson.

74. Defendants had a duty to create a device that was not unreasonably dangerous for its normal, intended use and breached this duty.

75. Defendants knew or should have known that the Recalled Devices, including the subject device, would be prescribed to patients and that physicians and patients were relying on them to furnish a suitable device. Further, Defendants knew or should have known that patients for whom the Recalled Devices would be used, such as Kemetha Richardson, could be and would be affected by the defective design and composition of the devices.

76. Defendants researched, designed, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective device which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Kemetha Richardson, and Defendants are therefore strictly liable for the injuries sustained by her.

77. As a direct and proximate result of Defendants' placement of the subject device into the stream of commerce and Kemetha Richardson's use of the product as designed,

manufactured, sold, supplied, and introduced into the stream of commerce by Defendants, Kemetha Richardson suffered serious physical injury and death..

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT II
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

78. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

79. Plaintiff pleads this count under Mississippi's product liability act, Miss. Code. Ann. §11-1-63.

80. At all times herein mentioned, Defendants designed, developed, researched, tested, and knew or should have known about significant liver disease risks with subject device.

81. At all times herein mentioned, Defendants advertised, promoted, marketed, sold, and distributed the subject device that was used by Kemetha Richardson.

82. The subject device was expected to and did reach the usual consumers, handlers, and persons encountering said device without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

83. Defendants each had an independent duty and continuing duty to warn the medical community and Kemetha Richardson's physicians about the significance of the risks of disease, cancer and other health harms with the subject device.

84. Kemetha Richardson used the subject device in a manner intended and foreseeable by Defendants.

85. The subject device was defective due, in part, to inadequate warnings because Defendants knew or should have known that the product created a significantly increased risk of disease, cancer, among other health impacts, and failed to warn the medical community and Kemetha Richardson's physician of the nature of such risks.

86. Defendants omitted and downplayed the significantly increased risks of disease, cancer and other health risks with the subject device that Defendants knew or should have known from previous testing and research even prior to subject device's FDA approval.

87. The subject device's labeling and warnings were defective because they omitted and inadequately warned of the device's risk of disease, cancer and other health risks.

88. Although physicians are supposed to weigh the risks and benefits before prescribing a medical device, Defendants knew that their deliberate omissions would cause physicians, including Kemetha Richardson's physician, to prescribe the subject device without being able to adequately weigh the risk of device's risk of disease, cancer and other health risks.

89. If Defendants would have properly warned about the subject device's liver disease risk and/or other health harms, no reasonable physician, including Kemetha Richardson's physician, would have recommended or prescribed the subject device because the potential benefits of weight loss are significantly outweighed by the risk of disease and/or other harms.

90. Had Defendants reasonably provided adequate warnings of disease, such warnings would have been heeded and no healthcare professional, including Kemetha Richardson's physician, would have prescribed the subject device and no consumer, including Kemetha Richardson's, would have purchased and/or used the subject device.

91. As a direct and proximate result of the subject device's defects as described herein, Kemetha Richardson developed liver disease, suffered permanent and continuous injuries, pain and suffering, disability and impairment and death.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT III
STRICT LIABILITY – MANUFACTURING DEFECT

92. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

93. Plaintiff pleads this count under Mississippi's product liability act, Miss. Code. Ann. §11-1-63.

94. At all times herein mentioned, Defendants were involved in researching, designing, developing, manufacturing, testing, selling and/or distributing the Recalled Devices, including the subject device, which are defective and unreasonably dangerous.

95. The subject device was expected to and reached Kemetha Richardson without a substantial change in its condition.

96. The finished subject device deviated, in terms of construction and quality, from the specifications or planned output in a manner that made it unreasonably dangerous.

97. At all relevant times, the Recalled Devices, including the subject device, were defectively and improperly manufactured and designed by Defendants in that Defendants continued to supply consumers with the Recalled Devices despite having full knowledge that the devices posed substantial and avoidable bodily injury, including liver disease.

98. The foreseeable risks of the subject device were known and could have been avoided.

99. At all relevant times, the subject device was defectively manufactured by Defendants in that its design and formulation is more dangerous than what an ordinary consumer would expect when used in an intended and reasonably foreseeable manner.

100. At all relevant times, Defendants actively deceived users that their use of the Recalled Devices posed safety risks that far outweighed any benefits.

101. Furthermore, the Recalled Devices, including the subject device, were defectively manufactured in that the PE-PUR foam comprising part of the devices can degrade into particles that enter the devices' air pathway and can off-gas certain chemicals. These characteristics cause, among other problems, liver disease. Kemetha Richardson and other similarly situated consumers were unknowingly subjected to receiving different doses of toxins, carcinogens, and other deleterious components and contaminants when using the Recalled Devices.

102. As a direct and proximate result of the defective manufacture of the subject device, Kemetha Richardson suffered damages for which Plaintiff is entitled to recover, including but not limited to compensatory damages, consequential damages, interest, costs, and attorneys' fees.

COUNT IV
NEGLIGENT DESIGN

103. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

104. Plaintiff pleads this count under Mississippi's product liability act, Miss. Code. Ann. §11-1-63.

105. At all relevant times, Defendants manufactured, designed, marketed, tested, promoted, supplied, sold and/or distributed the Recalled Devices, including the subject device, in the regular course of business that Kemetha Richardson purchased.

106. The subject device was designed and intended to be used for the treatment of sleep apnea and other health issues.

107. Defendants knew or by the exercise of reasonable care, should have known, the use of the subject device was dangerous, harmful and injurious when used by Kemetha Richardson and consumers in a reasonably foreseeable manner.

108. Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Kemetha Richardson would not have realized the potential risks and dangers of the subject device.

109. Defendants breached their duty by failing to use reasonable care in the design of the subject device by designing the device such that PE-PUR foam inside the device could produce highly harmful particles and gasses that enter the device's airway leading to the user's respiratory system.

110. The subject device contained and produced chemicals and particles which can lead to headaches, irritation of the skin, eye, and respiratory tract, inflammation respiratory issues, asthma, adverse effect to organs (including the kidneys and liver), hypersensitivity, nausea, vomiting, and toxic and cancer, all of which Defendants knew, or by the exercise of reasonable care, should have known, would affect ordinary consumers such as Kemetha Richardson.

111. Defendants breached their duty when they failed to use commercially-feasible alternative designs to minimize these harms, including but not limited to designing products that prevented exposure to particles and off-gasses from PE-PUR foam, using a kind of noise and

vibration reducing foam that did not possess these harmful qualities, using alternative methods of noise vibration reduction, preventing foam particles and gasses from entering the airway of the product, among many other potential designs.

112. Defendants breached their duty by failing to use reasonable care by declining to include an expiration or best if "used by" date, which left open the potential for the devices' chemical and other properties to change in an even more harmful manner.

113. As a direct and proximate result of the subject device's defects as described herein, Kemetha Richardson developed liver disease, suffered permanent and continuous injuries, pain and suffering, disability and impairment and death.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT V
NEGLIGENT FAILURE TO WARN

114. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

115. At all relevant times, Defendants designed, manufactured, assembled, inspected, tested (or not), packaged, labeled, marketed, advertised, promoted, supplied, distributed, and/or sold the Recalled Devices, including the subject device that Kemetha Richardson used.

116. The Defendants knew or, by the exercise of reasonable care, should have known, use of the subject device was dangerous, harmful, and injurious when used by Kemetha Richardson in a reasonably foreseeable manner.

117. The Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Kemetha Richardson would not have realized the potential risks and dangers of the subject device.

118. The Defendants knew or, by the exercise of reasonable care, should have known, that the Recalled Devices posed risks including headaches, irritation of the skin, eye, and respiratory tract, inflammation respiratory issues, asthma, adverse effect to organs (including the kidneys and liver), hypersensitivity, nausea, vomiting, and toxic and cancer, among other harmful effects, as described herein, that were known and knowable in light of scientific and medical knowledge that was generally accepted in the scientific community at the time of design, manufacture, and distribution of the Recalled Devices.

119. The Defendants owed a duty to all reasonably foreseeable users to disclose the risks associated with the use of the Recalled Devices.

120. The Defendants breached their duty of care by failing to use reasonable care in providing adequate warnings to Kemetha Richardson's physician, in the subject device's labeling and packaging, and through marketing, promoting, and advertising of the subject device.

121. At all relevant times, Defendants could have provided adequate warnings and instructions to prevent the harms and injuries set forth herein, such as providing full and accurate information about the Recalled Devices to physicians, to patients, in advertising, at point of sale, on the devices' instructions and inserts, and on the devices' labels.

122. A reasonable company under the same or similar circumstances would have warned and instructed of the dangers.

123. Kemetha Richardson was injured as a direct and proximate result of Defendants' failure to warn and instruct because she would not have used or purchased the subject device had

she received adequate warnings and instructions that she could be exposed to toxic and carcinogenic particles and gasses that cause headaches, irritation of the skin, eye, and respiratory tract, inflammation respiratory issues, asthma, adverse effect to organs (including the kidneys and liver), hypersensitivity, nausea, vomiting, toxic chemicals, and cancer.

124. Defendants' lack of adequate and sufficient warnings and instructions and its inadequate and misleading advertising, labeling, and instructions to physicians was a substantial contributing factor in causing the harm to Kemetha Richardson.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, medical monitoring to diagnose subject device induced injuries at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VI
NEGLIGENT MANUFACTURING

125. Plaintiff adopts and incorporates by reference the foregoing language of this Complaint as if fully set forth herein and further states as follows.

126. Plaintiff pleads this count under Mississippi's product liability act, Miss. Code. Ann. §11-1-63.

127. At all relevant times, the Defendants designed, manufactured, assembled, inspected, tested (or not), packaged, labeled, marketed, advertised, promoted, supplied, distributed, and/or sold the Recalled Devices, including the subject device that Kemetha Richardson used.

128. The Defendants had a duty to use exercise reasonable care in the manufacturing, assembling, inspecting, and packaging of the subject device.

129. The Defendants knew or, by the exercise of reasonable care, should have known, use of the subject device carelessly manufactured, assembled, inspected, and packaged was dangerous, harmful and injurious when used by consumers, such as Kemetha Richardson, in a reasonably foreseeable manner.

130. The Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Kemetha Richardson would not have realized the potential risks and dangers of the subject device improperly manufactured assembled, inspected, and packaged.

131. Without limitation, the Defendants breached their duty to exercise reasonable care in manufacturing, assembling, inspecting, and packaging the Recalled Devices by their:

- Failure to follow Good Manufacturing Practices ("GMPs");
- Failure to adequately inspect/test the Recalled Devices during the manufacturing process;
- Failure to adequately determine/test the integrity of PE-PUR foam and its qualities, especially after the devices have aged.
- Failure to adequately determine/test the purity of airflow through the Recalled Devices' airway, especially after the devices have aged.

132. A reasonable manufacturer under the same or similar circumstances would have implemented appropriate manufacturing procedures to better ensure the quality of their devices.

133. Kemetha Richardson was injured as a direct and proximate result of Defendants' failure to use reasonable care in the manufacturing, assembling, inspecting, and packaging of the subject device as described herein.

134. The Defendants' negligent manufacturing, assembling, inspecting, and packaging of the subject device was a substantial factor in causing Kemetha Richardson's harms.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, medical monitoring to diagnose subject device induced injuries at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VII
NEGLIGENCE/GROSS NEGLIGENCE

135. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

136. Defendants had a duty to exercise reasonable care in designing, developing, researching, testing, manufacturing, marketing, supplying, promoting, selling, and distribution of the Recalled Devices, including the subject device.

137. Defendants knew or should have known that using the subject device created a significantly increased risk of liver disease, among other health harms.

138. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

- Defendants designed and developed the Recalled Devices without thoroughly or adequately testing the devices;
- Defendants sold the Recalled Devices without making proper and sufficient tests to determine the dangers to the users;
- Defendants failed to adequately and correctly warn Kemetha Richardson, the public, and the medical community, of the liver disease risks associated with the Recalled Devices;

- Defendants advertised and recommended the use of the Recalled Devices for treatment of sleep apnea and other conditions without sufficient knowledge as to the significance of liver disease risks;
- Defendants failed to exercise reasonable care in designing the Recalled Devices in a manner which was dangerous to the users;
- Defendants negligently manufactured the Recalled Devices in a manner which was dangerous to the users;
- Defendants failed to exercise reasonable care when they collectively decided to conceal information concerning liver disease risks.

139. Additionally, Defendants under-reported, underestimated, and downplayed the serious dangers of the Recalled Devices' association with liver disease and other health harms.

140. Defendants negligently compared the safety risk and/or dangers of the subject device with other forms of treatment for sleep apnea and similar conditions.

141. Defendants also failed to warn Kemetha Richardson, prior to actively encouraging the sale of the subject device, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early detection of liver disease.

142. Defendants specifically failed to exercise reasonable care when they failed to accompany the subject device with proper and/or accurate warnings regarding *all* adverse side effects—namely liver disease—associated with the use of the subject device.

143. Once Defendants gained additional information about the Recalled Devices' association with liver disease, it failed to update its warnings and thereafter accompany the Recalled Devices with adequate warnings regarding kidney disease and liver disease.

144. Despite the fact that Defendants knew or should have known that the Recalled Devices caused unreasonably dangerous side effects, like liver disease, they made conscious decisions to downplay these risks and continue to market, manufacture, distribute, and/or sell the devices to physicians and patients, including Kemetha Richardson.

145. Defendants knew or should have known that consumers, such as Kemetha Richardson, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

146. Defendants' negligence was the proximate cause of Kemetha Richardson's liver-related injuries, among many other health harms, which Kemetha Richardson suffered.

147. As a result of the foregoing acts and omissions, Kemetha Richardson was caused to suffer serious and dangerous side effects that led to her liver disease and death.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT VIII
NEGLIGENT MISREPRESENTATION

148. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

149. Defendants had a duty to exercise reasonable care to those whom they provided device information about the Recalled Devices and to all those relying on the information provided, including Kemetha Richardson, her healthcare providers, and the public in general that the devices had been tested and found to be safe and effective for treating sleep apnea.

150. Defendants, in the course of selling the Recalled Devices, supplied information about the devices through television commercials, advertisements, marketing campaigns, sales representatives, labeling, and warnings.

151. Defendants breached their duty by misrepresenting the Recalled Devices' safety to the medical and healthcare community, to Kemetha Richardson, and the public in general.

152. However, Defendants failed to exercise reasonable care because their goal should have been to put safety before their profits by providing individuals with the realistic risks and expectations that the Recalled Devices could cause liver disease and other serious injuries.

153. Defendants' representations were made without properly conducting sufficient testing and by providing insufficient warnings about the Recalled Devices' potential risks.

154. Defendants' false representations that the Recalled Devices were safe for consumers and their failure to disclose material past and existing facts of the Recalled Devices' risk of liver disease were made or omitted with the intent to induce Kemetha Richardson to rely upon those facts or omissions.

155. Kemetha Richardson was unaware and did not know that the subject device was unsafe for the purpose of treating sleep apnea because it caused a significant increased risk of liver disease until *after* she had been exposed to carcinogenic particles and gasses.

156. Kemetha Richardson justifiably relied upon the false representations of Defendants.

157. Had Defendants reasonably and proposed provided adequate warnings of liver disease and other serious injuries, such warnings would have been heeded and no healthcare professional, including Kemetha Richardson's physician, would have prescribed the Recalled Devices and no consumer, including Kemetha Richardson, would have purchased and/or used the Recalled Devices.

158. As a direct and proximate result of the foregoing acts and omissions, Kemetha Richardson was caused to suffer serious and dangerous side effects, including liver disease and death.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT IX
FRAUD

159. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

160. At all relevant times, Defendants designed manufactured, assembled, inspected, tested, packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold and/or otherwise placed the Recalled Devices into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to consumers, such as Kemetha Richardson.

161. Defendants knowingly made fraudulent statements regarding the safety of the Recalled Devices and the substantial health risks associated with using the devices, all the while intending to deceive Kemetha Richardson and the general public.

162. At all reasonable times, Defendants fraudulently misrepresented the Recalled Devices as safe, when in fact the devices posed unreasonable risks of substantial bodily injury. Due to these and other features, the Recalled Devices are not fit for their ordinary, intended use as treatment devices for sleep apnea and similar respiratory conditions.

163. Defendants touted the Recalled Devices as safe, despite a failure to adequately research or test the devices to assess their safety prior to marketing and promoting their use.

164. Defendants further falsely represented the nature and risks associated with the Recalled Devices, and their marketing and strategy regarding the same, in general statements to the media, general public, and federal agencies.

165. Defendants' fraudulent misrepresentations and omissions were material facts that were essential to Kemetha Richardson's decision to purchase the subject device.

166. Kemetha Richardson was unaware that Defendants were knowingly concealing these material facts, which Kemetha Richardson relied on to her detriment.

167. By knowingly misrepresenting this material information, Defendants breached their duty to protect Kemetha Richardson and consumers.

168. Kemetha Richardson justifiably relied to her detriment on Defendants' fraudulent statements. Had she been adequately informed of the material facts concealed from her regarding the safety of the subject device, and not intentionally deceived by Defendants, she would not have acquired/purchased or used the subject device.

169. As a direct and proximate result of Defendants' fraudulent misrepresentations, Kemetha Richardson suffered from the injuries and damages for which Plaintiff is entitled to recover, including but not limited to compensatory damages, consequential damages, interest, costs, and attorney fees.

COUNT X
FRAUDULENT CONCEALMENT

170. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

171. At all relevant times, Defendants designed, manufactured, assembled, inspected, tested, packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold and/or

otherwise placed the Recalled Devices into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to those that used the devices, such as Kemetha Richardson.

172. Defendants had a duty to disclose material facts about the Recalled Devices that would substantially affect Kemetha Richardson's and the general public's use when purchasing the devices.

173. At all reasonable times, Defendants fraudulently misrepresented the Recalled Devices as safe, when in fact the devices posed unreasonable risks of substantial bodily injury. Therefore, the devices are not fit for their ordinary and intended uses.

174. Defendants actually knew about all of the above facts.

175. At all relevant times, Defendants fraudulently and deceptively concealed their failure to adequately research or test the Recalled Devices to assess their safety before marketing to susceptible users.

176. Defendants further falsely represented the nature and risks associated with the Recalled Devices, and their marketing and strategy regarding the same, in general statements to the media, general public, and federal agencies.

177. Defendants' misrepresentations and omissions were material facts that were essential to Kemetha Richardson's decision making when purchasing and using the subject device.

178. Kemetha Richardson was completely unaware that Defendants were concealing these material facts.

179. Defendants intentionally deceived and concealed material information concerning the safety of the Recalled Devices from Kemetha Richardson and the general public, which had a direct impact on Kemetha Richardson's and consumers' health and wellbeing.

180. Kemetha Richardson relied to her detriment on Defendants' fraudulent concealment and omissions. Had Kemetha Richardson been adequately informed of the material facts regarding the safety of the Recalled Devices, and not intentionally deceived by Defendants, she would not have acquired/purchased, used, or been injured by the subject device.

181. As a direct and proximate result of Defendants' fraudulent concealment, Kemetha Richardson suffered from the injuries and damages for which Plaintiff is entitled to recover, including but not limited to compensatory damages, consequential damages, interest, costs, and attorney fees.

COUNT XI
CIVIL CONSPIRACY

182. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

183. Defendants knowingly agreed, contrived, confederated, and/or conspired to defraud Kemetha Richardson and consumers of the Recalled Devices regarding the true nature of the devices and their potential to cause liver disease and other serious injuries associated with the PE-PUR foam's particles and chemicals when the devices were used in a reasonably foreseeable manner.

184. Defendants knowingly agreed, contrived, confederated, and/or conspired to defraud Kemetha Richardson and consumers of the Recalled Devices with the purpose of maintaining the popularity and reputation of the devices and therefore maintaining high sales, at the expense of consumer safety.

185. At all relevant times, pursuant to and in furtherance of said conspiracies, the Defendants performed the following overt and unlawful acts:

a. Defendants designed and sold the Recalled Devices with full knowledge that the devices were not a safe way to treat sleep apnea.

b. Upon information and belief, despite available medical and scientific data, literature, and test reports possessed by and available to Defendants, Defendants individually, jointly, and in conspiracy with each other, fraudulently, willfully, and maliciously, to delay reporting to the public the issues and delay the product recall. In the meantime, Defendants continued to represent the Recalled Devices as safe and omitted warnings about serious side effects.

186. Kemetha Richardson and the general public reasonably relied upon the aforementioned fraudulent representations, omissions, and concealments made by the Defendants regarding the nature of the Recalled Devices.

187. Were it not for Defendants' unlawful actions to mislead the public and limit the natural dissemination of scientific research and knowledge on the dangers and harms associated with the Recalled Devices, Kemetha Richardson and the general public could have learned of the dangers at an earlier date and potentially prevented their introduction to and use of the devices.

188. As a direct and proximate result of Defendants' overt unlawful acts regarding the nature of the Recalled Devices which were made pursuant to and in furtherance of a common scheme, and Kemetha Richardson's reliance thereon, Kemetha Richardson suffered from the injuries and damages for which Plaintiff is entitled to recover, including but not limited to compensatory damages, consequential damages, interest, costs, and attorney fees.

COUNT XIII
BREACH OF EXPRESS WARRANTIES

189. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

190. The Defendants, through their advertising, promotional materials, and labeling, expressly warranted and affirmed that the Recalled Devices were safe for their intended uses and for uses which were reasonably foreseeable.

191. Defendants' representations became a basis of the bargain.

192. Defendants made express warranties which extended beyond delivery of the Recalled Devices and expressly warranted for future performance of the devices. Defendants advertised, promoted, and labeled the Recalled Devices as being safe and effective for the treatment of sleep apnea.

193. At all relevant times, Defendants breached said express warranties in that the Recalled Devices were unsafe and caused liver disease among other harms. Kemetha Richardson foreseeably used the subject device without knowing of the harmful and substantial consequences to her health.

194. At all relevant times, Defendants had knowledge of the hazards and health risks posed by the Recalled Devices when used.

195. At all relevant times, Defendants willfully failed to disclose the defects and health risks of the Recalled Devices to Kemetha Richardson and the rest of the public that used the devices.

196. In reliance upon the express warranties made by Defendants, Kemetha Richardson acquired/purchased and used the subject device, believing the subject device was inherently safe and/or a safe treatment for sleep apnea.

197. Kemetha Richardson notified Defendants of the breach.

198. As a direct and proximate result of Defendants' breach of their express warranties concerning the subject device, Kemetha Richardson suffered injuries and death for which Plaintiff is entitled to recover, including but not limited to compensatory damages, consequential damages, interest, costs, and attorneys' fees.

COUNT XIV
BREACH OF THE IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

199. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

200. At all relevant times, Defendants, through their advertising and promotional materials, expressly and impliedly warranted and affirmed that the Recalled Devices' purpose was to offer a reasonably safe treatment for sleep apnea and similar health problems.

201. Defendants touted the Recalled Devices as safe, despite knowingly having never adequately researched or tested the devices to assess their safety before placing the devices on the market and promoting them to consumers.

202. Defendants intended to make Kemetha Richardson and the general public believe the Recalled Devices were safe.

203. Defendants knowingly mislead Kemetha Richardson and the general public to believe the Recalled Devices were safe for use, despite knowing that the devices could lead to

serious injuries, all of which Defendants knew, or by the exercise of reasonable care, should have known, ordinary consumers such as Kemetha Richardson would be victim to.

204. At all relevant times, Defendants had knowledge of the hazards and health risks posed by the Recalled Devices when used.

205. At all relevant times, Defendants willfully failed to disclose the defects and health risks of the Recalled Devices to Kemetha Richardson and the consuming public.

206. Kemetha Richardson relied to her detriment on the information publicized by Defendants.

207. In reliance upon these implied warranties as to the safety of the subject device by Defendants, Kemetha Richardson acquired/purchased and used the subject device, believing that the subject device was inherently safe.

208. Kemetha Richardson notified Defendants of the breach.

209. As a direct and proximate Defendants' warranties concerning the subject device, as described herein, Kemetha Richardson suffered injuries and death for which Plaintiff is entitled to recover, including but not limited to compensatory damages, consequential damages, interest, costs, and attorneys' fees.

COUNT XV
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

210. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

211. At all relevant times, Defendants have been a merchant in regard to the Recalled Devices they created and sold to consumers.

212. Defendants breached their implied warranty of merchantability since the Recalled Devices were defective when created and designed, and do not conform with the promises represented on their labels.

213. Defendants failed to comply with merchantability requirements, as the Recalled Devices do not achieve the ordinary purposes they advertise: a healthy treatment for respiratory conditions such as sleep apnea.

214. Beyond Defendants' own direct sales of the Recalled Devices, Kemetha Richardson and other consumers are third-party beneficiaries of Defendants' agreements with its distributors, dealers, and sellers for the distribution, dealing, and sale of the Recalled Devices to consumers. Kemetha Richardson and other consumers are the intended beneficiaries of Defendants' implied warranties since the Recalled Devices are manufactured with the express and intended purpose of selling the devices to consumers.

215. As a direct and proximate result of Defendants' breach of their implied warranties of merchantability regarding the subject device, Kemetha Richardson was injured because, had she been aware of the unmerchantable condition of the subject device, she would not have acquired/purchased the subject device and not suffered injuries and damages from its use, for which Plaintiff is entitled to recover, including but not limited to compensatory damages, consequential damages, interest, costs, and attorneys' fees.

COUNT XVI
VIOLATION OF THE MISSISSIPPI CONSUMER PROTECTION ACT

216. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

217. Kemetha Richardson is a "consumer" as defined in Miss. Code Ann. §75-24-1 in that she acquired/purchased, other than for purposes of resale, goods from the Defendants.

218. Defendants' actions in marketing, advertising, and otherwise making public representations about the subject device constitute "trade" as they were actions that created, altered, repaired, furnished, made available, provided information about, or, directly or indirectly, solicited or offered for or effectuated a sale, lease, or transfer of consumer goods.

219. At all relevant times, the Defendants knew or should have known of the unreasonably dangerous nature of the subject device.

220. At all relevant times, Defendants, through their labeling, promotion, and marketing of the Recalled Devices, intentionally misrepresented material facts in order to mislead consumers that the devices were safe and effective for the treatment of sleep apnea.

221. Defendants mislead consumers regarding the substantial health risks associated with using the Recalled Devices constituting a misrepresentation of unlawful trade practices.

222. Defendants falsely represented themselves when claiming that the Recalled Devices did not pose unreasonable and substantial risks to their health, and thus violated the Mississippi Consumer Protection Act by marketing their goods or services to be of a particular standard, quality, grade, style, when they are/were in fact another.

223. Kemetha Richardson acted in reasonable reliance upon Defendants' unlawful trade practices through Defendants' misrepresentations and omissions. Had Defendants not engaged in the deceptive conduct described herein, reasonable consumers and Kemetha Richardson would not have acquired/purchased the Recalled Devices if they had known the devices posed unreasonable and substantial risks to their health. Knowledge of these material factors would have highly

impacted Kemetha Richardson's decision when first acquiring/purchasing and using the subject device.

224. Defendants omitted material facts misleading consumers about the safety and efficacy of the Recalled Devices, thus violating the Mississippi Consumer Protection Act.

225. As a direct and proximate result of the unlawful trade practices of Defendants, in violation of the Mississippi Consumer Protection Act, Kemetha Richardson suffered damages and death for which Plaintiff is entitled to recover, including but not limited to compensatory damages, consequential damages, treble or per-violation damages, interest, costs, attorneys' fees, and all other available damages.

PUNITIVE DAMAGES

226. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

227. Defendants' conduct described herein consisted of oppression, fraud, and/or malice, and was done with advance knowledge, conscious disregard of the safety of others, and/or ratification by Defendants' officers, directors, and/or managing agents.

228. Despite their knowledge of the Recalled Devices' propensity to cause liver disease and other serious injuries, Defendants chose profits over the safety of American citizens suffering with sleep apnea when they sought to create and market a device posing significant health risks.

229. Despite having substantial information about the Recalled Devices' serious and unreasonable side effects, Defendants intentionally and recklessly failed to adequately warn the public, physicians, and the medical community.

230. Further, despite having substantial information about the Recalled Devices' serious and unreasonable side effects, Defendants failed to make the decision to pull the devices

from the market after receiving indications and after receiving reports from consumers who were experiencing serious injuries associated with the use of the devices.

231. Defendants downplayed and recklessly disregarded their knowledge of the defective nature of the Recalled Devices' potential for causing serious injuries.

232. Defendants chose to do nothing to warn the public about serious and undisclosed side effects with the Recalled Devices.

233. Defendants recklessly failed to warn and adequately instruct physicians, including Kemetha Richardson's physician, regarding the increase in reports from consumers who were experiencing serious injuries associated with the use of the Recalled Devices.

234. Consequently, Defendants are liable for punitive damages in an amount to be determined by the jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants jointly and severally for damages, including punitive damages if applicable, to which he is entitled by law, as well as all costs of this action, interest and attorneys' fees, to the full extent of the law, whether arising under the common law and/or statutory law, including:

a. Judgment for Plaintiff and against Defendants;

b. Damages to compensate Plaintiff for Kemetha Richardson's injuries, economic losses and pain and suffering and death sustained as a result of the use of Defendants' subject device;

c. Pre and post judgment interest at the lawful rate;

d. Punitive damages, if applicable, on all applicable Counts as permitted by the law;

e. A trial by jury on all issues of the case;

f. An award of attorneys' fees; and

g. For any other relief as this Court may deem equitable and just, or that may be available under the law of another forum to the extent the law of another forum is applied, including but not limited to all reliefs prayed for in this Complaint and in the foregoing Prayer for Relief.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and as to all issues.

Dated: December 9, 2021

Respectfully Submitted,

By: /s/ Richard Freese
Richard A. Freese (MS Bar #99885)
FREESE & GOSS PLLC
1901 6th Avenue North Suite 3120
Birmingham, AL 35203
(205) 871-4144
(205) 871-4104 – Fax
rich@freeseandgoss.com

Calle M. Mendenhall (*pro hac vice*)
FARRIS RILEY & PITT, LLP
505 20th Street North, Suite 1700
Birmingham, Alabama 35203
(205) 324-1212 - Phone
(205) 324-1255 – Fax
cmendenhall@frplegal.com

Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this action.

By: /s/ *Richard Freese*
Richard Freese